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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,350	05/22/2001	Francis X. Ignatious	00537-181002	5160

37903 7590 03/29/2007
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/744,350

Applicant(s)

IGNATIOUS, FRANCIS X.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/14/06
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19-32 and 49-62 is/are pending in the application.
- 4a) Of the above claim(s) 23, 24, 26, 27, 30-32 and 49-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19-22, 25, 28, 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/2006 has been entered.

Status of Claims

There is no change in the status of the claims.

Claims 17,19-32,49-62 are pending. Claims 23,24,26,27,30-32,49-62 remain withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 and the dependent claims 19-22,25,28,29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 17 introduces new matter as it introduces an unsupported specific

Art Unit: 1631

negative limitation to exclude polyesters which are "not a carboxy-terminated polyester".

A negative limitation must have basis in the original disclosure. Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), 738 F.2d 453 (Fed. Cir. 1984). MPEP 2173.05 (I) instructs that any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Note that as "carboxy-terminated polyesters" are not positively recited in the specification, they may not be explicitly excluded in the claims.

The examiner has not found *ipsis verbis* support for this negative claim limitation in the specification. Applicant directs attention to p. 16, lines 1-4; however, said section does not provide support for this newly introduced negative limitation. With respect to showing in US 5,672,659 (incorporated by reference), Fig. 2, addressed by applicant, depicts the product of interacting peptide salt with a polyester, whereas the subject of negative limitation is the polyester interacting with the salt of peptide, i.e., before the interaction. The latter are exemplified on Fig. 1 as all having terminal carboxy group. Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. MPEP 2173.05(i). In the instant case, US 5,672,659 does not provide a disclosure of alternative elements, i.e., disclosure of both carboxy-terminated and not carboxy-terminated polyesters interacting with peptide salts.

Art Unit: 1631

Further, the negative limitation finds no anchor in the explicit claim language. The express text of the claims does not prohibit the polyester from being carboxy-terminated. The phrase “polyester is not a carboxy-terminated polyester” finds no support in the text of the claims. Applicant must cancel the new matter in response to this rejection.

Response to arguments

Applicant discusses examples in US 5,672,659, which is a reference addressed on p. 19 of the specification and is incorporated by reference, and makes a conclusion that the reference provides an *ipsis verbis* support for the negative limitation “to exclude polyesters which are not a carboxy-terminated polyester” (emphasis added). However, following applicant’s reasoning, by excluding “polyesters which are not a carboxy-terminated polyester”, the remainder of the genus is a carboxy-terminated polyester, i.e., exactly the subject matter being excluded by the proposed negative limitation.

The subsequent discussion on pages 11, 12 of the response continues to pursue the issue that polyester can be and is described as a carboxy-terminated polyester and that this lends support for a limitation to exclude “polyesters which are not a carboxy-terminated polyester”. Again, the negative limitation reads on polyesters which are anything BUT carboxy-terminated polyesters, i.e., to the contrary from what being discussed by applicant.

Further, with respect to showing in US 5,672,659, Fig. 2, addressed by applicant, depicts the product of interacting peptide salt with a polyester, whereas the subject of negative limitation is the polyester interacting with the salt of peptide, i.e., before the interaction. The latter are exemplified on Fig. 1 as all having carboxy group.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. MPEP 2173.05(i). In the instant case, US 5,672,659 does not provide a disclosure of alternative elements, i.e., disclosure of both carboxy-terminated and not carboxy-terminated polyesters interacting with peptide salts.

Status of claim rejection under 35 USC § 103

Rejection of claims 17,19-22,25,28,29 under 35 U.S.C. 103(a) as being unpatentable over Hutchinson et al in view of Okada et al or Stap et al and further in view of Shalaby et al is withdrawn in view of amendment to the claim 17 disclaiming "carboxy-terminated polyesters". The rejection will be re-applied upon removal of new matter introduced by the amendment (see above).

It is noticed that the negative limitation is introduced to distinguish the claims from the primary reference, Hutchinson et al (US 5,889,110) used in the art rejection of record. Note, however, that the elected species of polyester in the instant invention is

Art Unit: 1631

anionic polylactide-co-glycolide containing COOH groups (i.e., carboxy group not necessarily located at C-terminus of the polyester), and that, as discussed in the rejection, polylactide-co-glycolide is the preferred anionic polyester used in Hutchinson et al.

This is an RCE of applicant's earlier Application No. 09/744350. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.

Primary Examiner

Art Unit 1631

mlb